REMARKS

1. Applicant thanks the Examiner for his remarks and observations.

2. Claim 1 stands rejected under 35 USC § 103(a) as being unpatentable over Guglielmi in view of Slepian. Applicant respectfully disagrees.

A. The current rejection suffers most of the defects as that made in the Final Rejection issued on October 7, 2003. While the Examiner has reversed the references, he still has not pointed to a suggestion or motivation in the prior art other than that the teachings were old and well known. Applicant again refers to the legal precedent cited in the Response of December 7, 2003. As the Federal Circuit has found, "[m]ost, if not all patentable inventions are novel combinations of known elements; there is only one standard of obviousness for all types of inventions." *Panduit Corp. v. Dennison Mfg. Co.* (*Panduit II*), 810 F.2d 1561, 1575 (Fed. Cir. 1983). Furthermore, "[i]t is immaterial to the issue, however, that all of the elements were old in other contexts. What must be found obvious to defeat the patent is the claimed invention." *Kimberley-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1448 (Fed. Cir. 1984). Thus, a statement that the separate elements of the invention are old and well known, and that the combination would be obvious to one having an ordinary level of skill does not establish a *prima facie* case of obviousness.

B. Again, the Examiner supports his finding of obviousness by concluding that the claimed invention would have been obvious in view of the references. However, the fact that the references "teach that all aspects of the invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references." MPEP § 2143.01. Here, the Examiner has not pointed to any objective reason to combine the references.

C. Additionally, obviousness can only be established "where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." MPEP § 2143.01. Here, beyond a conclusion that the invention would have been obvious, the Examiner hasn't pointed to any teaching or suggestion to combine the teachings of Guglielmi and Slepian..

D. An additional requirement for a finding of obviousness is a reasonable expectation of success: a recognition, either express or implied, in the prior art, or drawn from convincing reasoning based on scientific principles or legal precedent that an advantage or beneficial result would be produced by the combination. MPEP § 2143.02. Here, the Examiner concludes that the invention would have been obvious, failing to point to any advantage or beneficial effect resulting from the combination.

E. Although Guglielmi teaches application of heat to tissues, one skilled in the art would not be lead to Slepian to supply a way of applying heat because Guglielmi already teaches how to do it:

> RF energy may be applied to the cage so that when the cage is placed in a large body lumen, it serves as a collapsible RF antenna. As the body lumen shrinks on the cage, the cage compliantly yields while continuing to deliver RF energy to the body lumen until the desired amount of shrinkage is obtained.

Col. 4, line 27 to line 32, emphasis added.

Thus, there is no teaching or suggestion in Guglielmi that the method of heating tissue described therein needs to be supplemented or replaced by another method. Accordingly, one having an ordinary level of skill would not be motivated to look to Slepian for a way of heating tissue.

F. Additionally, there is no motivation to look to Slepian because Slepian teaches away from the combination. Slepian describes an apparatus and a product for endoluminal use, the primary object of which is to dilate and maintain the lumen of body structures such as blood vessels and to combat re-stenosis. Thus, Slepian's primary object is the exact opposite of Guglielmi's. On this fact alone, one having an ordinary level of skill would not be lead to the combination.

Furthermore, Slepian extensively discusses the disadvantages posed by use and retention of wire stents within the body, exactly the type of structure described by Guglielmi. Col. 3, line 47 to Col. 4, line 50. On this fact alone, one having an ordinary level of skill would not be lead to the combination.

Moreover, Slepian uses heated fluid diffused into the tissue lumen to provide local heating specifically because it affects the expansile member without affecting the surrounding

tissu . Col. 9, line 53 to line 58. Thus, one of Slepian's most important objects is not to shrink the tissue. Accordingly, one having an ordinary level of skill in the art would not be led to combine the teachings of Slepian and Guglielmi to derive the Claimed Invention.

G. The claimed combination cannot change the principle of operation of the primary reference or render it unsuitable for its intended use. MPEP § 2145. In this case, Guglielmi uses the very basket that is being placed as an RF antenna to apply energy to the tissue, thereby heating the tissue. Thus, Guglielmi heats the tissue by applying electromagnetic energy. In stark contrast, Slepian applies heat by means of simple heat transfer, allowing a heated fluid to diffuse into the lumen. Accordingly, modifying Guglielmi according to Slepian would impermissibly alter Guglielmi's principle of operation. Additionally, the heat energy from Slepian's heated fluid would be insufficient to shrink the tissue around the wire basket. Thus, the modification would render Guglielmi unsuitable for its intended use.

In view of the above, the rejection of Claim 1 and all Claims depending therefrom under 35 USC § 103(a) is deemed to be improper.

2. Claims 1, 2, 8, 14 20 and 23 stand rejected under 35 USC § 103(a) as being unpatentable over United States Patent No. 5,938,660 ("Swartz") in view of Guglielmi. Applicant respectfully disagrees. The Examiner attempts to establish a prima facie case of obviousness here by referring back to the above rejection. Because the Examiner failed to establish a *prima facie* case of obviousness above, it is impossible to use that rejection as a basis for establishing a *prima facie* case here. Moreover, even if the above rejection were not improper, because it is based on a different combination of references, it is impossible to establish a *prima facie* case here by simply referring back to that rejection without explaining specifically why the current combination of references renders the invention obvious.

In fact, by referring back to the previous rejection, the Examiner brings the same deficiencies forward, including:

A. A statement that the separate elements of the invention are old and well known and that the combination would be obvious to one having an ordinary level of skill does not establish a *prima facie* case of obviousness.

B. The Examiner has not pointed to any objective reason to combine the references.

C. Th Examin r hasn't pointed to any teaching or suggestion to combine the teachings of Swartz and Guglielmi.

D. The Examiner fails to point to any advantage or beneficial effect resulting from the combination.

E. The Examiner relies on Col. 1, line 44-54 of Swartz as teaching "exuding from said catheter a substance capable of perfusing into at least some tissue in said localized region; allowing said substance to perfuse into a tissue of said localized region; emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance." Applicant respectfully disagrees. Swartz describes an apparatus that is used to ablate tissue, either within the chambers of the heart, or within a blood vessel such as the pulmonary vein. Swartz includes an electrode that emits electromagnetic energy. A fluid conducts electromagnetic energy from the electrode to the tissue, whereby the electromagnetic energy ablates the tissue. That is, it destroys the tissue. The invention, in stark contrast, is concerned with treating the tissue through the application of heat energy. Energy is applied to a flowable substance, which heats the flowable substance. The temperature change in the flowable substance exerts its therapeutic effect on the tissue. Guglielmi, as described above, uses a wire basket as an antenna to deliver RF -- electromagnetic energy-- to the tissue. The tissue shrinks around the wire basket and the wire basket is left in place. Thus, Guglielmi fails to teach exuding from said catheter a substance capable of perfusing into at least some tissue in said localized region; allowing said substance to perfuse into a tissue of said localized region; emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance." Nor do the references in combination teach the features of Claim 1. Therefore, there is no teaching or suggestion of the Claimed invention in the references, either separately or in combination. Accordingly, the rejection of Claim 1 under 35 USC § 103(a) and all Claims depending therefrom is deemed to be improper.

3. Claim 3 stands rejected under 35 USC § 103(a) as being unpatentable over Swartz in view of Guglielmi and further in view of WO 85/02779 ("Goffinet"). Applicant respectfully disagrees. Because the Examiner has failed to establish a prima facie case of obviousness based on the combination of Swartz and Guglielmi, the current rejection is also deemed improper.

4. Claim 24 stands rejected as being unpatentable over Guglielmi in view of Slepian and further in view of United Stat s Patent No. 5,423,744 ("Gencheff"). Because the Examiner has failed to establish a prima facie case of obviousness based on the combination of Slepian and Guglielmi, the current rejection is also deemed improper.

5. Claim 33 stands rejected under 35 USC § 103(a) as being unpatentable over Swartz in view of Guglielmi and further in view of United States Patent No. 5,971,983 ("Lesh"). Because the Examiner has failed to establish a prima facie case of obviousness based on the combination of Swartz and Guglielmi, the current rejection is also deemed improper.

CONCLUSION

In view of the foregoing, the Application is deemed to be in allowable condition. Therefore, Applicant earnestly requests the Examiner to withdraw all rejections, allowing the Application to pass to issue as a United States Patent. Should the Examiner have any questions regarding the Application, he is urged to contact Applicant's attorney at 650-474-8400.

Respectfully submitted,

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AMENDMENTS TO THE CLAIMS

1. (Previously amended) A method for treating a dilatation of a body, including the steps of:

inserting a catheter into a localized region of said body;

exuding from said catheter a substance capable of perfusing into at least some tissue in said localized region;

allowing said substance to perfuse into a tissue of said localized region; emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance; and

contracting said dilatation;

whereby at least some tissue in said localized region is treated.

2. (Original) A method as in claim 1, wherein said localized region includes a lumen or sphincter.

3. (Original) A method as in claim 1, wherein said localized region includes cancerous, engorged, inflamed or infected tissue.

4. (Withdrawn) A method as in claim 1, wherein said localized region includes an aneurysm, a blocked lumen, a stenosed lumen or a constricted lumen.

5. (Withdrawn) A method as in claim 1, wherein said localized region includes a cyst, tumor or wart.

6. (Original) A method as in claim 1, wherein said localized region is associated with a body system, said body system including a blood vessel, lung tube, lung pocket, gastrointestinal system, urogenital system, nerve or nerve sheath.

7. (Withdrawn) A method as in claim 1, wherein said localized region is associated with a particular organ including a kidney, prostate, retinal lesion or skin lesion.

8. (Original) A method as in claim 1, wherein said exuded substance includes a saline solution.

9. (Withdrawn) A method as in claim 1, wherein said exuded substance includes a non-toxic foam.

10. (Withdrawn) A method as in claim 1, wherein said exuded substance includes a collagen.

11. (Withdrawn) A method as in claim 1, wherein said exuded substance includes a bioactive substance, said substance including a drug or enzyme.

12. (Withdrawn) A method as in claim 1, wherein said exuded substance includes a chemoactive substance including an acid, lipid-breaker or soap.

13. (Withdrawn) A method as in claim 1, wherein said exuded substance includes an instrumentative substance including a florescent or x-ray marker.

14. (Original) A method as in claim 1, wherein said energy is emitted by electrical contact.

15. (Withdrawn) A method as in claim 1, wherein said emitted energy includes RF (monopolar or bipolar), microwave or laser.

16. (Withdrawn) A method as in claim 1, wherein said emitted energy includes ultrasound.

17. (Withdrawn) A method as in claim 1, wherein said emitted energy includes physical heating or cooling.

18. (Original) A method as in claim 1, wherein said treatment includes shrinkage of said lumen or said sphincter to a selected dimension.

19. (Original) A method as in claim 1, wherein said treatment includes shrinkage of said lumen or said sphincter to a substantially normal dimension.

20. (Original) A method as in claim 1, wherein said treatment includes shrinkage of said engorged or inflamed tissue by removal of lipids or water,

21. (Withdrawn) A method as in claim 1, wherein said treatment includes shrinkage of said engorged or inflamed tissue by removal of an ablated tissue or a dead cell matter.

22. (Withdrawn) A method as in claim 1, wherein said treatment includes shrinkage of said engorged or inflamed tissue by removal of infection products.

23. (Original) A method as in claim 1, wherein said treatment includes destruction of a damaged or a diseased tissue.

24. (Original) A method as in claim 1, wherein said treatment includes promotion of epithelial growth.

25. (Original) A method as in claim 1, wherein said treatment avoids local nerve centers.

26. (Original) A method as in claim 1, including an additional step of isolating said localized region using a structure inserted as part of said catheter.

27. (Original) A method as in claim 26, wherein said inserted structure includes an occluding balloon.

28. (Original) A method as in claim 26, wherein said inserted structure includes a space-filling balloon with a lumen through it.

29. (Original) A method as in claim 1, wherein said catheter includes instrumentation used

for feedback.

30. (Original) A method as in claim 29, wherein said feedback includes surgical visualization provided by a camera, RF energy, x-rays, florescence or ultrasound.

31. (Original) A method as in claim 29, wherein said feedback includes systemic, comprising measurement of pH, pressure or temperature.

32. (Original) A method as in claim 29, wherein said feedback includes monitoring for said treatment, including an element for determining a location of a specified tissue element to be treated.

33. (Original) A method as in claim 29, wherein said feedback includes monitoring for said treatment, including pacing.

34. (Original) A method as in claim 1, wherein said exuding and perfusing includes a physical method of delivery.

35. (Original) A method as in claim 34, wherein said exuded and perfused substance includes included in a saline solution or nontoxic foam.

36. (Original) A method as in claim 34, wherein said physical method of delivery includes a porous balloon, a microporous balloon, or a balloon with a porous or microporous membrane.

37. (Original) A method as in claim 34, wherein said physical method of delivery includes direct emission from said catheter.

38. (Withdrawn) A method as in claim 34, wherein said physical method of delivery includes a local structure, comprising an absorbable basket or a stent.